

### **REMARKS**

Claims 1 - 10 are currently pending. Claims 5 - 10 were previously withdrawn. In the Office Action dated July 9, 2008, the title was objected to based on an alleged misspelling of a term. Also, claims 1 - 4 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable in view of Hoorn et al. (US 6,835,853) (hereinafter, "Hoorn"). Claims 1 - 4 were also rejected under § 103(a) as allegedly unpatentable over Fujikura et al. (AT 397,960) (hereinafter, "Fujikura"). The title has been amended to address the Examiner's objection. Claims 1 - 4 have been amended to more clearly articulate what is being claimed therein. No new matter has been added.

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

#### **I. Objection to the Title**

Applicants have amended the title to include the term tamsulosin as suggested by the Examiner and to better focus the title on the subject of non-withdrawn claims. Based on this amendment, Applicants respectfully assert that the misspelling has been fully addressed and request the Examiner withdraw the objection.

#### **II. Rejections based on 35 U.S.C. § 103(a)**

##### **A. The Pending Application Is Not Obvious In Light the Cited References**

In response to the rejections asserted by the Examiner, claim 1 has been cancelled and the limitations of claim 1 have been incorporated into claims 2 - 4. Claim 2 is now an independent claim on which claims 3 - 4 depend. The Examiner concedes that neither Hoorn nor

Fujikara describes the content of the impurities in a tamsulosin hydrochloride product reaction mixture. This is true because neither Hoon nor Fujikara are specifically concerned with the matter of avoiding overalkylated products in particular concentrations in a reaction mixture. In contrast, a primary focus of claims 2 - 4 is the minimization of certain deleterious overalkylated products. Neither Hoon nor Fujikara provide any motivation to minimize the concentration of these overalkylated products. In contrast, Applicants specifically teach the desirability of minimizing **overalkylated products**, not just any impurity or byproduct. Thus, although Hoon, Fujikara, and Applicants' disclosure generally describe the production of tamsulosin hydrochloride, a specific and novel feature of Applicants' invention is to minimize the presence of overalkylated byproducts in the reaction mixture.

**B. The Examiner Has Not Made Out a Prima Facie Case of Obviousness**

Applicants also respectfully assert that the Examiner has not made out a *prima facie* case of obviousness because, among other things, the reasons for rejecting claims 2 - 4 have not been explained with sufficient clarity. "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." MPEP § 2142. In reference to the dependent claims, the Examiner simply states: "the limitations in *some* of the dependent claims, not expressly taught in the art, are also deemed to be obvious." The Examiner does not even indicate *which* dependent claims contain the alleged obvious limitations and saying the claims are "deemed" to be obvious is far too conclusory to discharge the Examiner's duty to clearly articulate why the art would be viewed to render the claims obvious. Also, the term "some" is used, which implies that not all of the dependent claims contain alleged obvious limitations. Which claims are not rejected? Applicants are left to guess which dependent claims the Examiner is referring to with regard to the obviousness rejections of claims 2 - 4.

The Examiner further states that "[o]ne of ordinary skill in the art would be motivated to *tweak and optimize these parameters* to arrive at the instantly claimed invention" (emphasis added). It is unclear what the Examiner means by "these parameters" considering that the

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elected claims at issue are composition claims and not process claims, and her disparagement of Applicants' invention as involving merely "tweaking [sic]" and "optimizing" is unwarranted and improper. Neither Hoorn nor Fujikara even hints at the desirability that impurities in the nature of overalkylated products should be avoided. No cited art describes or suggests compositions meeting the requirements of the claims, nor has the Examiner pointed to any even arguable suggestion of the claimed subject matter sufficient to raise a prima facie case of obviousness.

In light of the foregoing, Applicants respectfully request the Examiner reconsider the application, withdraw the rejections, and issue a notice of allowance at the earliest possible convenience.

If the Examiner identifies further issues which may be resolved by telephone, the Examiner is invited to contact the undersigned at (865) 546-4305.

In the event that this response is not timely filed, Applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any other fees which may be due with respect to this response, may be charged to our Deposit Account No. 12-2355.

Respectfully submitted,  
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